Specifically, the alleged additional disclosure is a kit which comprises a nucleic acid comprising a gene encoding p21 and a catheter.

Applicants respectfully traverse the Examiner's denial of priority. In order to comply with the written description requirement, the specification need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the filing date the applicant had invented what is claimed. Eiselstein v. Frank, 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995).

In addition, material may be incorporated by reference into a patent application. Ex parte Schwarze, 151 USPQ 426 (Bd. App. 1966). "Essential material" is defined as that which is necessary to (12) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode. Manual of Patent Examining Procedure §608.01(p). "Nonessential material" is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art. Id. Both essential and nonessential material may be incorporated by reference to a United States patent. Id.

The Examiner admits that the Applicants' disclosure provides support for the use of a catheter and an expression vector comprising a gene encoding p21 in a treatment method. Applicants submit that the term "kit" is well-known and often used in the art of describe known combinations of items. Moreover, kits are included in the present application via the disclosure of U.S. Patent No. 5,328,470.

The '470 patent (column 14, line 43 to column 15, line 19) discloses methods and kits for the site-specific delivery of various compositions. Such kits include, for example, a kit comprising an expression vector and catheter. The '470 patent (column 15, lines 5 – 19) also specifically discusses the use of kits containing either single-balloon or double-balloon catheters.

The Applicants' specification thus further recognizes that catheters and nucleic acids can be combined as kits. The Applicants also disclose that the administration of p21 may be accomplished in variety of ways and correctly incorporate the '470 patent by reference to further illustrate such procedures, some of which involve the use of kits including a catheter and an expression vector. Applicants therefore submit that they have met the requirements of 35 U.S.C. §112, first paragraph, regarding written description in their priority documents.

Applicants also submit that, because of their description of the combination of a catheter and an expression vector comprising a gene encoding p21, including the proper incorporation by reference of the '470 patent, no new matter was introduced by the addition of kit claims 17 – 36. Withdrawal of the Examiner's denial of priority is respectfully requested for the reasons stated above.

#### OATH/ DECLARATION

The Examiner states that the application presents a claim for subject matter not originally claimed or embraced in the statement of the invention and

requires a new oath/ declaration. Applicants submit that as a result of the incorporation by reference of the '470 patent, and for the reasons stated above with respect to priority, no new matter is presented. Hence, withdrawal of the Examiner's request for a new oath/ declaration is respectfully requested.

#### **SEQUENCE COMPLIANCE**

Applicants' note the Examiner's statement, in the September 12, 2002

Office Action, indicating that the sequence listing in paper and computer readable forms has been entered.

## 35 U.S.C. §112, FIRST PARAGRAPH REJECTIONS

Claims 17 – 36 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, claim 17, and dependent claims 18 – 36, are directed to a kit comprising a catheter and a nucleic acid comprising a gene encoding p21. The Examiner admits that the Applicants' disclosure provides support for the use of a catheter and an expression vector comprising a gene encoding p21 in a treatment method but alleges that the specification provides no implicit or explicit support for a kit comprising a catheter and a nucleic acid comprising a gene encoding p21.

The Examiner also alleges that the specification provides no implicit or explicit support for claim 18, directed to a kit comprising a catheter and a nucleic acid comprising a gene encoding p21, wherein the catheter is a single-balloon catheter.

Applicants respectfully traverse the Examiner's rejection. As discussed above with respect to Applicants' priority claim, the specification discloses a combination of a catheter and a nucleic acid encoding p21 and teaches that such combinations may be included in a kits. Applicants submit that they have met the requirements of 35 U.S.C. §112, first paragraph, regarding written description. Withdrawal of the Examiner's 35 U.S.C. §112, first paragraph rejection is requested for the reasons stated above.

# 35 U.S.C. §112, SECOND PARAGRAPH REJECTIONS

Claims 21 and 32 – 33 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 21 stands rejected as allegedly providing insufficient antecedent basis for the term "the pharmaceutical carrier." Applicants have amended claim 21 to depend upon claim 20 instead of claim 17. No new matter has been added in the amended claim. In view of this amendment, Applicants request that the Examiner withdraw the 35 U.S.C. §112, second paragraph, rejection of claim 21.

Claim 32 is allegedly indefinite because the term "genetic therapeutics" is not defined in the specification and is not an art-recognized term used to define a

particular class of proteins. Applicants have amended claim 32 to replace the term "genetic therapeutics" with the term HLA-B7. No new matter has been added in the amended claim. Support for the amendment is found in the specification page 11, line 21. In view of this amendment, Applicants request that the Examiner withdraw the 35 U.S.C. §112, second paragraph rejection of claim 32 and dependent claim 33.

### **CLAIM REJECTIONS UNDER 35 U.S.C. §102**

Claims 17 and 19 – 36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Nabel et al. (U.S. Patent No. 5,863,904) ("the '904 patent"). Applicants respectfully traverse the Examiner's rejection. In view of the arguments made above with respect to the priority of the instant application, Applicants submit that this application is entitled to a priority date of September 26<sup>th</sup>, 1995. Accordingly, the '904 patent, which issued on Jan 26, 1999 cannot anticipate the present claims because it was not published more than one year prior to the filing date of the present application. Applicants therefore request that the Examiner withdraw the 35 U.S.C. §102(b) rejection of claims 17 and 19 – 36.

#### DOUBLE PATENTING REJECTIONS

Claims 17 and 19 - 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 8 of U.S. Patent No. 5,863,904.

Claims 17 and 19 - 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 15 of U.S. Patent No. 6,218,372 in view of U.S. Patent No. 5,863,904.

Claims 17 and 19 - 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 3 of U.S. Patent No. 6,057,300 in view of U.S. Patent No. 5,863,904.

Applicants enclose a Terminal Disclaimer in compliance with 37 C.R.F. 1.321(c) that disclaims the term of the patent that will issue from this patent application that extends beyond the term of U.S. Patent Nos. 5,863,094, 6,057,300 and 6,218,372. Applicants therefore request that the Examiner withdraw the above obviousness-type double patenting rejections.

In reply to the Office Action dated September 12, 2002, favorable reconsideration and allowance of this application are respectively requested for the reasons set forth in the above remarks. If, for any reason, the Examiner is unable to allow the application on the next Office Action and feels that an interview would be helpful to resolve any remaining issues, he is respectfully requested to contact the undersigned attorney at (312) 321-4229.

Respectfully submitted,

Dated: December 12, 2002

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# VERSION WITH MARKINGS TO SHOW CHANGES MADE. IN THE CLAIMS

- 21. (Once amended) The kit of claim [17] <u>20</u>, wherein the pharmaceutical carrier comprises the nucleic acid.
- 32 (Once amended) The kit of claim 31, wherein the second gene encodes HLA-B7, an immunotherapeutic agent, [generic therapeutic,] cytokine, or prodrug converting enzyme.